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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/068,664

02/06/2002

Chuan Li

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03/09/2005

EXAMINER

KETTER, JAMES S

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ART UNIT

PAPER NUMBER

1636

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

416

## Office Action Summary

Application No.

10/068,664

Applicant(s)

LI, CHUAN

Examiner

James S. Ketter

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-20 is/are pending in the application.
- 4a) Of the above claim(s) 5-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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15 ~~16~~ Claims 5-~~16~~ stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 12 January 2004.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lereclus (A, newly cited).

The instant claims are drawn to a plasmid comprising at least a replication origin and a selection marker gene that has only sequences that are of known and desirable function, which did not use a whole existing plasmid as a starting material for its synthesis nor referred to the entire structure of an existing plasmid. Claim 17 is drawn to a fragment comprising said plasmid, claim 18 is drawn to a vector comprising said plasmid, and claim 19 is drawn to a bacterial cell comprising the vector of claim 18.

Lereclus teaches, e.g., at the paragraph bridging columns 22 and 23, pHT1035, which is a plasmid synthesized from pieces of DNA so as to carry the pHT1030 replicon, cat<sup>R</sup> gene, and

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pBR322 origin of replication. At Figure 9, the plasmid is depicted linearly, i.e., as a fragment.

Also, transfection of E. coli is taught therein.

Claims 16-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitt et al. (B, newly cited).

The instant claims are drawn to a plasmid comprising at least a replication origin and a selection marker gene that has only sequences that are of known and desirable function, which did not use a whole existing plasmid as a starting material for its synthesis nor referred to the entire structure of an existing plasmid. Claim 17 is drawn to a fragment comprising said plasmid, claim 18 is drawn to a vector comprising said plasmid, and claim 20 is drawn to a eukaryotic cell comprising the vector of claim 18.

Whitt et al. teaches, e.g., at column 10, fourth full paragraph, a Rhabdoviral vector having the minimal replicon elements and N, P, L and M genes, to minimally function to replicate. However, the genes that produce infectious particles are not present. In, e.g., Example 1, infection of BHK cells with one such viral vector is taught.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 16 recites, and therefore dependent claims 17-20 are limited to, only “sequences of known functions”. However, it is not clear what is meant by this phrase. Any nucleic sequence in a vector would have at least one known function, that of mere structure, i.e., holding together two adjacent sequences. Conversely, it would not be clear that any sequence would be characterized so completely that all of its functions, no matter how slight or subtle, would be known. As such, the metes and bounds of the instant claim are not clear.

Claim 16 recites, and therefore dependent claims 17-20 are limited to, only “sequences of desirable functions”. However, it is not clear what is meant by this phrase. Any nucleic sequence in a vector would have at least one desirable function, that of mere structure, i.e., holding together two adjacent sequences. Conversely, presumably any sequence could be undesirable under some circumstances, i.e., it spuriously binds to another macromolecule, or it has no useful function in some particular context, and would merely add to the energy burden on the cell. As such, the metes and bounds of the instant claim are not clear.

Claim 16 recites, and therefore dependent claims 17-20 also recite, the phrase “without referring the entire structure of an existing plasmid”. However, the exact meaning of this phrase is not clear. This phrase could have been interpreted as meaning that no known elements or components of the plasmid were used, that the entire sequence of the plasmid was unknown, or that no direct polymerase synthesis, i.e., no DNA replication was performed using an existing plasmid as the replication template. (This grounds of rejection was not clearly set forth in the previous Office Action, and so is now presented as a discrete rejection.) One problem is the non-grammatical construction “referring...the structure”. When “refer” is used as a transitive verb, it means, for example, to send (to), such as “referring a patient to another doctor”. As the

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intransitive verb, it requires the preposition “to”, which would appear to be the sense intended here. However, even rewritten as “referring to...the structure”, were the claim so amended, the problems noted above would remain, as the meaning of “referring to” is still imprecise, having the multiple interpretations set forth above.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.


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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jsk  
March 4, 2005

  
JAMES KETTER  
PRIMARY EXAMINER